

REMARKS

Claims 1-21 are pending in the application. Claims 16-18 were previously withdrawn from consideration. Claims 1, 6, 10 and 15 have been amended by way of the present amendment. Reconsideration is respectfully requested.

In the outstanding Office Action, claims 1-3, 5-7, 12-15, 19 and 21 were rejected under 35 U.S.C. Section 102(b) as anticipated by U.S. Patent No. 3,605,123 (Hahn); and claims 9-11 were rejected under 35 U.S.C. Section 103(a) as unpatentable over Hahn.

102 Claim Rejections

Claims 1-3, 5-7, 12-15, 19 and 21 were rejected under 35 U.S.C. Section 102(b) as anticipated by Hahn. Applicants respectfully traverse the rejection.

Claim 1, 6, 10 and 15 have been amended to clarify the invention. In particular, claim 1 has been amended to recite:

wherein the layer is established on an undulating or uneven surface (3') present on the implant and having a roughness value in the range of 0.4 - 5 μm , for the purpose of increasing the layer volume, and

wherein the channel network (6) is designed with mouths (3, 4') which face towards a surface of the layer and whose respective cross-sectional diameters (D) are in the range of 0.1 μm to 10 μm at the surface (2a') of the layer and are substantially less than the respective extents (H) of the channels in and down into the layer as seen from said surface (2a'), and

wherein the diameters of the mouths and the extents of the channels stimulate bone growth by means of diffusion and contribute to the incorporation of the implant in the tissue structure.

Claim 15 has been amended with similar language. Support for the amendments is provided at least at page 8, line 24 to page 9, line 6, and shown at least in FIG. 4 of the specification.

Therefore, the amendments raise no questions of new matter.

Hahn discloses a permanent implant for bone tissue which has a dense cast or wrought base portion of high strength metal, and a porous metal layer overlying and bonded to the base portion.¹ In particular, Hahn discloses a prosthesis **10** that includes a pin or shaft **11** and ball **12**.² In addition, Hahn discloses the prosthesis **10** may be composed of metals such as titanium.³

Further, Hahn discloses the titanium prosthesis **10** is coated, on the pin or shaft **11**, with a *thin* porous layer of titanium **13**.⁴ In particular, Hahn discloses, that at the interface between the shaft **11** and layer **13** is, for practical purposes free of pores or interstices.⁵ Further, Hahn discloses that the pores will range from about 30 microns to about 200 microns wide at the opening or mouth.⁶ Furthermore, Hahn discloses that the coating thickness is approximately 0.1 inch and the preferred thickness is from about 0.015 to about 0.030 inches.⁷

Moreover, Hahn discloses a process for providing a high strength bond between the coating **13** and base metal shaft **11** using a plasma flame. In particular, Hahn discloses *no* porosity or practically no porosity exists at the interface between the coating **13** and surface of the base metal shaft **11** and gradually increasing porosity, along with pore size and pore density, in moving away from the interface between the surface of the base metal and the coating **13**. Furthermore, Hahn discloses renderings of actual photographs of magnified sections of bone **20**, **30**; pin or shaft **21** and coating **22**, **32**.⁸

However, Hahn nowhere discloses, as recited in claim 1:

wherein the channel network (6) is designed with mouths (4') which face towards a surface of the layer and whose respective cross-sectional *diameters (D) are in the range of 0.1 μ to 10 μ m* at the surface (2a') of the layer and are substantially less than the respective extents (H) of the channels in and down into the layer as seen from said surface (2a'), and

wherein the diameters of the mouths and the extents of the channels stimulate bone growth by means of diffusion and contribute to the incorporation of the implant in the tissue structure (emphasis added).

¹ Hahn at Abstract.

² *Id.* at column 3, lines 30-33.

³ *Id.* at column 3, lines 33-35.

⁴ *Id.* at column 3, lines 43-45.

⁵ *Id.* at column 3, lines 55-58.

⁶ *Id.* at column 3, lines 63-66.

⁷ *Id.* at column 3, lines 47-54.

⁸ *Id.* at FIG. 2, FIG. 3; column 3, lines 55-66; and column 5, lines 25-42.

That is, Hahn nowhere discloses “mouths (4’) which face towards a surface of the layer and whose respective cross-sectional *diameters (D)* are in the range of 0.1μ to 10μ a layer,” as recited in amended claims 1 and 15. In contrast to the claimed invention, Hahn discloses pores that will range from about 30 microns to about 200 microns wide at the opening or mouths.

In addition, though the outstanding Office Action suggest the implant can include a screw (not shown), it is respectfully submitted that Hahn nowhere discloses “an undulating or uneven surface *present on the implant* and having a roughness value in the range of $0.4 - 5\mu$,” as recited in amended claim 1 and claim 15. In contrast to the claimed invention, Hahn discloses a “normally smooth surface of the dense titanium member **10** is coated in the region **11**.”⁹ Further, Hahn nowhere discloses “the layer has high degree of porosity, with a number $1 \times 10^7 - 1 \times 10^{10}$ pores/cm³,” as recited in claim 9.

Thus, it is respectfully submitted that Hahn does not disclose, anticipate or inherently teach the limitations of claims 1-3, 5-7, 9, 12-15 and 19-21. Therefore, it is respectfully submitted that claims 1 and 15, and claims dependent thereon, patentably distinguish over Hahn.

103 Claim Rejections

Claims 9-11 were rejected under 35 U.S.C. Section 103(a) as unpatentable over Hahn. Applicants respectfully traverse the rejection.

Claims 9-11 are dependent on claim 1. As discussed above, claim 1 is not disclosed by Hahn. Therefore, at least for the reasons discussed above, claims 10 and 11 are not disclosed by Hahn.

The outstanding Office Action attempts to overcome the deficiencies of Hahn with the suggestion of obviousness.¹⁰ However, obviousness cannot overcome all of the deficiencies of Hahn as discussed below.

Claims 9-11 are ultimately dependent upon claim 1. However, Hahn nowhere discloses, as recited in claim 1:

⁹ Hahn at column 3, lines 42-44.

wherein the channel network (6) is designed with mouths (4') which face towards a surface of the layer and whose respective cross-sectional *diameters (D) are in the range of 0.1μ to 10μ* at the surface (2a') of the layer and are substantially less than the respective extents (H) of the channels in and down into the layer as seen from said surface (2a'), and

wherein the diameters of the mouths and the extents of the channels stimulate bone growth by means of diffusion and contribute to the incorporation of the implant in the tissue structure (emphasis added).

That is, Hahn nowhere discloses “mouths (4') which face towards a surface of the layer and whose respective cross-sectional *diameters (D) are in the range of 0.1μ to 10μ* a layer,” as recited in amended claims 1 and 15. In contrast to the claimed invention, Hahn discloses pores that will range from about 30 microns to about 200 microns wide at the opening or mouths.

Further, as discussed above, Hahn nowhere discloses a layer, “established on an undulating or uneven surface present on the implant and having a roughness value in the range of 0.4 - 5 μ m,” as recited in claim 1 (emphasis added).¹¹

In addition, claim 1 recites: “mouths (4') which face towards a surface of the layer and whose respective cross-sectional diameters (D) at the surface (2a') of the layer are substantially less than the respective extents (H) of the channels,” as recited in claim 1. Moreover, claim 1 recites: “*wherein the diameters of the mouths and the extents of the channels stimulate bone growth by means of diffusion and contribute to the incorporation of the implant in the tissue structure*” (emphasis added). It is respectfully submitted that Hahn nowhere explicitly addresses the dimensions of the channels (i.e., “D” and “H” as recited in claim 1) or any relationship between these dimensions or the use of the channels and mouths in contributing to the incorporation of the implant in the tissue.

Thus, it is respectfully submitted that Hahn nowhere discloses, suggests or makes obvious the limitations of claim 1 and claim 15, and even more specifically, the limitations of

¹⁰ Outstanding Office Action at page 9, lines 4-14.

¹¹ *Id.* at column 3, lines 55-66.

claims 9-11, which ultimately depend upon claim 1. Therefore, claims 9-11, and claims dependent thereon, patentably distinguish over Hahn.

Conclusion

In view of the above amendments and remarks, reconsideration and allowance of the pending claims are respectfully requested.

Applicants believe that the present application is in condition for allowance, and an early indication of the same is respectfully requested.

If the Examiner has any questions or requires clarification, the Examiner may contact the undersigned so that this Application may continue to be expeditiously advanced. In the event the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned is available at the telephone number noted below.

The Director is hereby authorized to charge any fees, or credit any overpayment, associated with this communication, including any extension fees, to Deposit Account No. 22-0185.

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Respectfully submitted,

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